



***A GUIDE
FOR REQUESTING
SECTION 18 EMERGENCY
EXEMPTIONS FROM
REGISTRATION IN
WASHINGTON
STATE***

***REGISTRATION SERVICES
PESTICIDE MANAGEMENT DIVISION
WASHINGTON STATE DEPARTMENT OF AGRICULTURE***

Rev. 5/13/2004

PART 1 – THE APPLICATION PROCESS

Emergency Pest Problems and the Section 18 Process

What happens when a new pest attacks your crop and there are no effective pesticides registered to control it? Or an unusual period of weather has promoted a pest problem that is out of the ordinary? Maybe the manufacturer of the only effective pesticide left for your crop has decided to no longer register the product? Or that devastating pest has finally developed resistance to the last effective product registered to control it?

These and other emergency situations occur every year in Washington State, and they do take their economic toll. However, Section 18 of FIFRA, a provision that allows the EPA under emergency circumstances to temporarily exempt a pesticide from the full requirements of registration, is designed to specifically deal with these emergency situations. Because the state of Washington is one of the leading minor crop states in the nation and grows over 300 different commercial crops, it is not surprising that we have our fair share of emergencies. The Washington State Department of Agriculture has a well developed program for obtaining emergency uses under Section 18.

If you are dealing with an urgent, non-routine pest problem and have no viable options for control, you may have a valid reason for requesting emergency use under Section 18 of FIFRA. This guide has been published to assist you in applying to WSDA for emergency exemption use. Applicants are also encouraged at any time to seek assistance from WSDA Pesticide Registration staff by calling (360) 902-2030 or email pestreg@agr.wa.gov.

When To Consider Requesting An Emergency Exemption

An emergency exemption from registration may be considered for situations in which an **“emergency condition”** exists. An emergency condition exists only when the situation is **urgent** and **non-routine** **AND** all three of the following conditions are met: (1) No effective registered pesticides are available, (2) no economically or environmentally feasible alternative practices are available, and (3) the situation involves the introduction of a new pest or will present significant risks to human health or the environment or will cause **significant economic loss**.

Requests for Section 18 emergency exemption use are normally compiled and submitted to WSDA by agricultural researchers, consultants, extension staff, and/or commodity organizations. Registrants of pesticide products often provide key information for the request, but the “emergency” must be the result of and driven by actual field conditions.

The EPA has established a 50-day period to review Section 18 requests. With requirements set forth in the FQPA, EPA’s review process has been slowed dramatically. WSDA also needs some time to review and compose a petition to EPA. As a rule of thumb, the following time lines should be observed when submitting a Section 18 request:

- Request for a repeat Section 18: submit to WSDA at least 80 days prior to the earliest use.
- Request for a new Section 18: submit to WSDA at least 120 days prior to the earliest use.

These are minimum time lines; the more time for Agency review, the better chance of obtaining emergency use by the time it is needed.

Regional Requests vs. State Requests

Under certain circumstances it may be expedient for state lead agencies in the Pacific Northwest to submit a Section 18 request to the EPA as a regional request to include two or all three of the Northwest states. There are a number of factors that are taken into consideration when WSDA makes a decision to join Oregon and/or Idaho in submitting a Section 18 request. It is important that commodity groups seeking to submit a regional request contact the WSDA before they begin working with the other state lead agencies.

What Is A “Crisis” Exemption And When Is It Appropriate To Ask WSDA To Declare A Crisis?

The word “crisis” and the word “emergency” may mean about the same thing in layman’s terms, but in FIFRA language, a “crisis” is only one of several types of emergencies regulated under Section 18. A “Crisis Exemption” is an exemption that is reserved for dire situations - those unanticipated emergency situations that seemingly occur overnight; situations where EPA does not have time to conduct a full review of a Section 18 request. The very nature of a Crisis Exemption excludes them from becoming commonplace.

Some groups have become habitually late in submitting Section 18 requests to WSDA. It is one thing to go crisis after EPA has exceeded their allotted review time, it is quite another to seek a crisis exemption on a repeat Section 18 simply because the request was not submitted to EPA in a timely fashion. Requesting a Crisis Exemption for a repeat Section 18 because of a tardiness in submitting the request is an unacceptable use of the Crisis provision.

PART 2 – JUSTIFYING THE EMERGENCY

Urgent and Non-Routine

In order to obtain Section 18 use, any emergency must be both urgent and non-routine. To be “urgent” and “non-routine” the situation must require immediate attention and be other than an ordinary one. Chronic or continually occurring pest problems are specifically excluded from the definition of an emergency condition.

The nature of the urgent, non-routine situation determines, in part, how long it would be expected to endure. Emergency situations brought about by unusual environmental conditions would not ordinarily be expected to occur in subsequent years (and therefore EPA would not normally expect repeat

requests). Other situations, such as those involving the loss of a registered pesticide, would likely continue until a new pesticide is registered.

It is important that a thorough explanation be given to explain all of the factors (other than mismanagement) that have caused the “urgent” and “non-routine” situation. Unusual weather patterns may be enough alone to justify an emergency; however, if there are other reasons for the emergency those reasons must also be included. For example, if pest resistance to available pesticides is building up, and the situation is exasperated by extreme weather conditions, both factors should be explained. If pest resistance is not discussed on the original request, the following year may experience normal weather patterns and there would be no justification for the emergency (even though pest resistance is occurring). It is a little suspicious and may be difficult to convince EPA that there is an urgent and non-routine situation when the reasons change each year (how did pest resistance come about overnight?). However, if all of the reasons are stated the first year, including any abnormal weather, the emergency may remain justified the second year or thereafter even if the weather has no bearing.

A recent trend has been to request multiple chemicals to address a specific emergency pest problem. Though pest resistance management is a concern, the EPA is not yet formally allowing this as justification for requesting multiple chemicals. Therefore, when requesting multiple chemicals it is necessary to thoroughly explain the justification. Essentially the justification must be that one chemical alone is not sufficient to control the pest problem, but the reasons for this must be thoroughly explained.

Availability of Effective Registered Pesticides

For each pesticide registered to control the pest problem, the applicant must demonstrate that it is either not effective or not available in adequate supplies. In most situations, efficacy claims must be supported by data; however, testimony of qualified experts may occasionally be used as a sole support of efficacy claims. Claims of unavailability of registered pesticides must be accompanied by a discussion of the attempts made to obtain adequate supplies.

Washington State University maintains a database of all pesticide products currently registered in the state of Washington (and Oregon). The “Pesticide Information Center On-Line” (PICOL) can provide a list of currently registered insecticides, herbicides, fungicides, rodenticides, etc., on almost any pest for any given crop in the Pacific Northwest. Applicants for Section 18’s are strongly encouraged to utilize PICOL to account for all possible registered alternatives to the Section 18 use requested. Failure to utilize PICOL information may cause unnecessary delays when WSDA reviews the Section 18 request. For further information contact the Pesticide Information Center, WSU Tri-Cities at (509) 372-7492 or on their web site at <http://picol.cahe.wsu.edu>.

Alternate Practices

Alternate practices available to control the pest problem must be identified and an explanation of their inadequacies must be presented. Alternate practices may include such things as mechanical, biological, cultural and other means of control.

Significant Economic Loss

A significant economic loss means a substantial reduction in normally expected profitability; or, for types of activities where profits cannot be calculated, a substantial reduction in the value of public or private fixed assets. In defining an emergency condition as one that is expected to result in a “significant economic loss”, the consequences must be more serious than a failure to maximize profits in a particular growing season.

Only those losses caused by the emergency condition are relevant in determining the expected economic loss. Losses due to obvious mismanagement are excluded from the loss estimate. Losses due to an agent other than the target pest problem are also excluded from the loss estimate.

The “normal range of profitability” refers to the range of profits for a productive activity over the past several years. Typically, the EPA requires 5 years of yield, price, and cost of production data to conduct an economic analysis on an emergency situation. The agency will compare expected profits under the conditions of the emergency with the historical “normal” range. If estimated profits are substantially below the normal range, the expected loss is considered significant.

The higher the variability in profits from year to year (the wider the historical profit range) the more difficult it is to demonstrate that there will be a significant economic loss caused by the emergency.

Occasionally an exceedingly poor year or good year causes a much wider historical range in profitability. This in turn can make it difficult to show that expected losses from the emergency situation will cause expected profitability to fall below the five year historical range. It is possible for EPA to take into account (throw out) such an abnormal fluctuation and adjust their economic analyses accordingly. In order for EPA to consider an abnormal year as being outside of the historical range of profitability, a thorough explanation must be submitted as to why the net profits during that particular year should not be considered part of the normal fluctuations in net returns.

Another important consideration in presenting economic information is to present data on the specific portion of a crop that is actually affected with the pest problem (and will actually be treated with Section 18 materials if approved). For example, if experts anticipate that a 20% reduction in yield will occur on 25% of the acreage, this is a very significant reduction in yield and more than likely will economically justify the emergency exemption for use on the 25% of the acreage with the problem. However, a 20% reduction on 25% of the acreage would only correspond to a 5% reduction in yield over the entire state-wide acreage. A 5% reduction in yield may not be enough to show a loss in expected profitability

that would fall below the historical range of profitability. Therefore, the economic data should be representative of the problem acreage that needs treatment.

Also, if there are any intangible losses that will be incurred but cannot be quantified, it is helpful to describe these in the narrative. These types of losses may not prove that use of a pesticide under emergency exemption is economically justified, but they can help to bolster the justification.

In the past, the department has received emergency exemption requests in which the cost of production per acre exceeded the gross revenue per acre. When this occurs, a detailed explanation is required.

Situations that are Not Justified as an Emergency

WSDA receives requests for emergency use each year that do not fulfill the requirements of a Section 18. Most often there is a clear need for a product to address a pest problem, but the pest problem does not meet the “non-routine” criteria established in federal regulation. Applicants often focus their attention on convincing WSDA that the product/use is needed, when in reality the request cannot be submitted to EPA because it does not meet the “non-routine” nature of a Section 18. Often these requests are made for new products that are undergoing the registration process, but have not received full registration by the EPA. Requesting Section 18 use for such products attempts to short-cut the registration process. WSDA sympathizes with the need, but must adhere to federal requirements. This is not to say that none of these request are legitimate. There are times when the non-routine nature of a pest emergency can be documented and a new product that is undergoing registration may be a good fit.

There are other situations when, clearly, a new product that is undergoing registration is a more efficacious and/or a less expensive alternative than what is currently registered. WSDA recognizes the value in obtaining the legal use of these products, but EPA does not consider such situations as meeting the “urgent” criteria of a Section 18 emergency.

PART 3 – SPECIFIC INFORMATION TO SUBMIT TO WSDA

The following sections coincide with the requirements of federal regulation. Each section contains a detailed description of the information that must be provided. Please submit the information in the following format (also see example request attached):

A. GENERAL INFORMATION

1. TYPE OF EXEMPTION: Whether a Specific, Quarantine, Public Health or Crisis Exemption.
2. CONTACT PERSONS: Identify knowledgeable experts who can be contacted for comment on (a) technical aspects and (b) economic aspects of the request. Include name, affiliation, address, telephone number, fax number, and e-mail address (if available).

3. **DESCRIPTION OF PESTICIDE:** Identify the active ingredient using the accepted American National Standards Institute (ANSI) name or the most accurate common chemical name.

For federally registered pesticides, specify the EPA Registration Number, registrant, and the name of the product.

If a specific product is not requested, specify the formulation(s) requested and the percent active ingredient. Provide a copy of the federally registered label and any additional labeling proposed for the emergency exemption use. In an effort to minimize processing time, products bearing labels previously approved by the EPA should be used whenever possible.

For all other pesticide products, the application should include a confidential statement of formula or reference to one already submitted to the EPA as part of a previous or pending action for the active ingredient (give EPA File Symbol, EUP number, or SLN number), and complete labeling which will be used in connection with the proposed exemption use.

Include a description of how unused material will be disposed of upon expiration of the emergency exemption.

4. **DESCRIPTION OF THE PROPOSED USE:** Specify all of the following:

- a. The site(s) to be treated: Describe the specific location within the state and provide as much detail as possible (e.g. proximity to water bodies, residences, etc.). Specify the geographical area (e.g. counties) where the emergency exists and names of counties (if not statewide) where applications will occur. When submitting an application to the EPA, the department must include a list of endangered or threatened species present in the areas to be treated. It is therefore important to provide detailed information regarding the location of the application sites.
- b. Method of application: Be as specific as possible, particularly if an innovative method which may reduce exposure will be used.
- c. Rate of application: Describe in terms of both active ingredient and formulated product.
- d. Maximum number of applications to be made under Section 18 use.
- e. Total acreage (or other appropriate units) expected to be treated under the exemption. Note: This should be the maximum acreage anticipated since EPA will limit the exemption accordingly.
- f. Total amount of pesticide to be used in terms of both active ingredient and formulated product.

g. Use period (or season): State the time for which use of the pesticide is requested. Be sure to explain if there are anticipated product production or distribution concerns that may delay getting product to the end user. The request cannot be for a time period greater than one year. Include the earliest anticipated harvest date.

h. All applicable restrictions, user precautions, qualifications of applicators and other requirements concerning the proposed use.

5. **ALTERNATIVE METHODS OF CONTROL:** List **all** pesticides that are registered for the proposed use, along with a detailed explanation of why each of these pesticides are not sufficient to control the emergency. If lack of efficacy is the reason given, field data demonstrating the ineffectiveness of the registered alternatives must be included. Under extenuating circumstances or in the absence of such field data, written statements from extension or university personnel, or other similarly qualified experts verifying the lack of efficacy may be acceptable. If an effective pesticide is available but not recommended by researchers, extension staff or other experts, an explanation of why it is not recommended must be provided. If a pesticide is recommended in the State or PNW pest control handbooks, but determined to be ineffective for this particular emergency situation, this discrepancy must also be explained.

If necessary application equipment is not available, an explanation of the attempt to obtain the equipment and the results of the attempt must be provided.

When a registered alternative is not available in sufficient quantity, provide an explanation of the attempts to obtain sufficient quantities.

The request must also contain a detailed explanation, supported by field data, of why it is not economically and/or environmentally feasible to employ alternative practices to resolve the emergency. For repeat uses, the use of an alternative practice (if available) is expected to be used in subsequent years to address an anticipated emergency instead of use of a pesticide under section 18 (e.g., rotating crops, using tolerant/resistant crop strains, preplant treatment, etc.). A request for a repeat use should indicate why such practice was not employed.

6. **EFFICACY DATA:** The request must contain data, a discussion of field trials, or other evidence (e.g. experimental testing, small plot trials, laboratory trials, or corroborating evidence from similar uses) which provided the basis for the conclusion that the proposed use will be effective.
7. **RESIDUE DATA:** If the requested use is for a food or feed crop or potable water, residue levels must be estimated. Residue levels must be estimated for all the food commodities even if residues in a processed food are expected to be lower than those in the treated commodity. The request shall address whether residues are expected in or on food, a list of the food item(s) likely to contain residues, and an estimate of the maximum amount of residues likely to result from the

proposed use. If residue levels are expected to be nondetectable, the request should so state and specify the limit of detection.

The residue data from which the above residue estimate is derived must be provided if not already on file with the EPA. If data are on file with the EPA, please provide the appropriate reference number (tolerance petition or MRID number).

If certain potential food/feed items will not be allowed into the marketplace, cite the method(s) for controlling distribution in the marketplace.

8. **RISK INFORMATION:** Include a detailed discussion of the potential risks from the proposed use. The discussion must address the potential risk to human health, endangered or threatened species, beneficial organisms, and the environment. A description of the application sites including proximity to aquatic systems, endangered species habitats, residences, etc., as well as soil type should be provided, along with references to data or other supporting information. Proposals to mitigate risk (protective clothing, setback restrictions, soil type restrictions, etc.) should be listed.

a. Human health:

(i) FQPA requires the EPA to consider aggregate exposure from multiple routes (food, water and the environment) when reviewing section 18 applications. The following information (most of which can be obtained from registrants) must be submitted with all food/feed use Section 18 requests:

- **Groundwater:** The request should include information and available modeling data on the persistence, mobility and chemistry for the product when there is a potential for transfer of residues to drinking water. It should also provide information on any drinking water monitoring program (monitoring, detections and limits of detection) in the state.
- **Residential Use:** Information on residential uses of the chemical.
- **Mode of Action:** Data on other pesticides with the same mode of action as the active ingredient being requested in the section 18.
- **Timing of Crop Harvest:** A time-limited tolerance must be established for all Section 18 food/feed uses. EPA needs to know the earliest anticipated harvest date to ascertain that they will be able to establish the time limited tolerance prior to harvest.

(ii) Any applicable Worker Protection Standard (WPS) requirements need to be addressed in the request and on proposed labeling.

b. Environmental Issues:

(i) General requirements: Environmental hazards will be identified in part 8 of the Section 18 request, and will be mitigated by statements as outlined in part 4 of the request. Environmental hazard mitigation statements will be required for pesticides that are toxic to fish or wildlife, or have the potential for contaminating ground water or surface water. These statements should be consistent with standard EPA language, unless WSDA determines that more specific restrictions are necessary. Environmental hazards that are adequately mitigated by the Section 3 label do not need to be mitigated on the Section 18 request.

(ii) Chemigation: A chemigation statement will be required for pesticides that will be applied through irrigation water. This statement should be consistent with standard EPA language, and should also refer to WSDA chemigation rules. If the Section 3 label already has a chemigation statement, then the Section 18 request does not require a chemigation statement (except a reference to the Section 3 label and WSDA chemigation rules).

(iii) Ecological Risk & Endangered species: In an effort to expedite use approval by EPA and US Fish & Wildlife Service, applicants must provide documentation that endangered species will not be adversely affected from the emergency use of a pesticide. WSDA's initial evaluation of a Section 18 request is based on the toxicity (LC_{50}) of the pesticide. Therefore, the LC_{50} data for freshwater fish and aquatic invertebrates **must** be submitted with every request (except for indoor use or seed treatment) on the WSDA Aquatic Risk Assessment form (<http://agr.wa.gov/PestFert/Pesticides/docs/AquatRiskAssess4129.pdf>).

Using the LC_{50} and the table below, WSDA evaluates the toxicity of the chemical. An ecological risk may exist if the LC_{50} indicates that the chemical is moderately to very highly toxic or phytotoxic and endangered species are present in the area to be treated. WSDA can then either impose default restrictions or the product can be evaluated using an alternative risk assessment approach, such as GENEEC (GENeric Estimated Environmental Concentration). When the GENEEC computer model (discussed in depth below) indicates that no adverse effects are predicted, then WSDA will not required default restrictions.

USEPA (FIFRA) hazard classifications

LC_{50} (ppm)*	Category Description
< 0.1	very highly toxic
0.1 - 1.0	highly toxic
>1 - 10	moderately toxic
>10 - 100	slightly toxic
> 100	practically nontoxic

* toxicity of compounds to aquatic organisms

Default restriction statements for emergency exemptions

Toxicity rating / species	Ground*	Airblast	Chemigation	Aerial
Moderately toxic to fish or aquatic invertebrates	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, 2. Leave a 10 foot untreated buffer between treatment area and fish-bearing waters, or 3. Use low pressure nozzles according to manufacturer's specifications that produce only coarse or very coarse droplets. 	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, or 2. Leave a 25 foot untreated buffer between treatment area and fish-bearing waters. 	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, or 2. Leave a 25 foot untreated buffer between treatment area and fish-bearing waters. 	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, or 2. Leave a 75 foot untreated buffer between treatment area and fish-bearing waters.
Highly to very highly toxic to fish or aquatic invertebrates	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, 2. Leave a 25 foot untreated buffer between treatment area and fish-bearing waters, or 3. Use low pressure nozzles according to manufacturer's specifications that produce only coarse or very coarse droplets. 	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, or 2. Leave a 50 foot (dormant) / 25 foot (foliated) untreated buffer between treatment area and fish-bearing waters. 	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, or 2. Leave a 50 foot untreated buffer between treatment area and fish-bearing waters. 	To protect endangered aquatic species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from fish-bearing waters, or 2. Leave a 150 foot untreated buffer between treatment area and fish-bearing waters.
Phytotoxic to aquatic or terrestrial plants**	To protect endangered plant species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from native plant communities, 2. Leave a 25 foot untreated buffer between treatment area and native plant communities, or 3. Use low pressure nozzles according to manufacturer's specifications that produce only coarse or very coarse droplets. 	Not applicable.	To protect endangered plant species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from native plant communities, or 2. Leave a 50 foot untreated buffer between treatment area and native plant communities. 	To protect endangered plant species, use one of the following options: <ol style="list-style-type: none"> 1. Apply only when there is sustained wind away from native plant communities, or 2. Leave a 150 foot untreated buffer between treatment area and native plant communities.

*Applications with backpack sprayers or other similar equipment are exempt from this requirement.

**An endangered species statement is not required if the plant is not susceptible to the herbicide (e.g. endangered plant species is a dicot and the herbicide is only active against monocot species).

Default restrictions are mitigation measures, which may include modifying product use rates, spatial restrictions (e. g. buffer zones to avoid endangered species habitats), or other measures that WSDA, EPA, and/or US Fish & Wildlife Service may impose. The table on the previous page lists WSDA's current default restrictions. No special restrictions will be required for products which are non-toxic or slightly toxic to threatened or endangered freshwater fish and aquatic invertebrates, nor for products which are non-phytotoxic to threatened or endangered plant species. For threatened or endangered species not listed on the previous page (e.g. mammals, reptiles, amphibians, birds or insects), WSDA will develop risk mitigation statements in cooperation with the appropriate agency.

Alternative Aquatic Risk Assessment Method

The GENEEC (GENeric Estimated Environmental Concentration) computer model may be used to predict the likelihood of no adverse effects on aquatic organisms from a particular pesticide under normal conditions of use. EPA uses the GENEEC model to calculate the estimated environmental concentrations for pesticides as a first level assessment that is designed to be protective (ECOFRAM, 1999 and Parker et. al, 1995).

GENEEC can be used to predict the estimated environmental concentration (EEC) of the chemical **if** the applicant submits the information cited on the Aquatic Risk Assessment Form (i.e. chemical and environmental fate properties of the compound, and aquatic organism toxicity data). The EEC is then used to calculate a Risk Quotient, as defined below, which indicates whether adverse effects on non-target organisms are expected.

The potential for acute or chronic adverse effects should be measured using the following calculation¹:

$$\text{Risk Quotients (RQ)} = \text{EEC} / \text{toxicity endpoint}$$

The toxicity endpoint is the LC₅₀. RQs should be calculated to define whether the proposed exposure exceeds acceptable levels of risk. When RQ values (both acute and chronic) are below the trigger value for endangered and non-endangered species, then no adverse effects on nontarget organisms are predicted under normal conditions of use of the labeled product. For evaluation of acute risk to each group of aquatic organisms being assessed (i.e. freshwater fish and aquatic invertebrates), the following chart will be used to determine whether there is a need to impose special requirements (mitigation measures):

Exposure type	Species	RQ Risk Criteria Value:	Results
Acute exposure	non-endangered	< 0.1	No Special Requirement - Level of Concern (LOC) is not exceeded when the RQ is less than the risk value
	endangered	< 0.05	
Chronic exposure	non-endangered & endangered	< 1.0	

If the risk assessment predicts possible adverse effects or the applicant/registrant does not provide information or data to demonstrate that endangered species will be adequately protected, then WSDA will impose the default restrictions based on the toxicity of the pesticide to mitigate possible adverse effects.

A copy of the GENEEC model for use on PC's may be requested from WSDA by sending an email request to pestreg@agr.wa.gov. The Aquatic Risk Assessment Form will be available on the internet at <http://www.wa.gov/agr/pmd/pesticides/forms.htm#req5>.

¹This assessment methodology is based upon USEPA guidance in the USEPA Standard Evaluation Procedure, Ecological Risk Assessment [Urban, D. and N. Cook (1986) EPA540/9-85-001].

(iv) Herbicides: Section 18 requests for herbicides should refer to WSDA herbicide rules, when appropriate. Requests for aquatic herbicides must include a statement on minimizing the potential for fish kills due to oxygen depletion from decaying vegetation.

(v) Insecticides: Section 18 requests for insecticides will require a pollinator protection statement if the insecticide is moderately or highly toxic to bees and the crop or site is attractive to bees. Refer to *POLLINATOR PROTECTION REQUIREMENTS FOR SECTION 18 EMERGENCY EXEMPTIONS AND SECTION 24(c) SPECIAL LOCAL NEED REGISTRATIONS IN WASHINGTON STATE*.

9. NOTIFICATION OF REGISTRANT: The request should include a letter from the registrant or manufacturer of the pesticide indicating that they support (or at least are aware of) the request. This letter might also include information on the progress towards registration of the proposed use (see number 13).

10. NOTIFICATION OF OTHER AGENCIES (standard language): The US Fish & Wildlife Service and the Washington State Departments of Ecology, Health and Fish & Wildlife have received copies of this request. Any comments received will be forwarded to the US EPA.

11. ENFORCEMENT PROGRAM (standard language): WSDA has adequate authority for enforcing provisions of Section 18 Emergency Exemptions and has been doing so for many years. We would be glad to answer any specific questions regarding our enforcement program.

12. PREVIOUS USE UNDER SECTION 18: If an emergency exemption has previously been granted an interim report summarizing the results of previously issued exemption(s) shall be included. List the year(s) in which previous exemption(s) were granted. Also list the requests that have been submitted to the department where the exemption was never granted.

Use Reporting Requirement: EPA regulations (40 CFR, Part 166) require that a final report be submitted that summarizes the results of the pesticide use under an emergency exemption. Generally, WSDA requests submission of a use report by the applicant within 30 days of the report due date in the EPA granting document and/or at least 80 days before the first use date of the next request. The timely delivery of this report to WSDA is the responsibility of the person, organization, or commodity group that submitted the Section 18 application. Future requests will not be submitted to the EPA until a use report from Washington is received. The report must include (1) total quantity of pesticide used (2) the rate per acre or other measure, and (3) Total number of acres treated. The final report should discuss the effectiveness of the pesticide in dealing with the emergency condition, any adverse effects resulting from the section 18 use, and any other information requested by EPA.

13. PROGRESS TOWARD REGISTRATION: Include a discussion of the progress being made toward registration of the proposed use. A summary of deficiencies and data gaps and the registrant's timetable for rectifying the deficiencies must also be included in the discussion.

If a complete application for federal registration of the proposed use, which has been under an emergency exemption for any three previous years, has not been submitted, the EPA will assume reasonable progress toward registration has not been made. This standard applies to uses which have been requested for any three previous years, regardless of whether the requests were granted or denied.

EPA may exercise its discretion whether or not reasonable progress toward registration has been made on IR-4 minor food uses. Generally, IR-4 minor food uses will be judged against a 5-year standard.

B. REQUIREMENTS FOR SPECIFIC EXEMPTIONS BASED ON SIGNIFICANT ECONOMIC LOSS

1. PEST(S) TO BE CONTROLLED: Include the scientific and common name of the pest or pest complex for which use of the pesticide is sought.
2. EVENTS WHICH BROUGHT ABOUT THE EMERGENCY CONDITIONS: Include a DETAILED discussion of all the events which brought about the emergency (weather conditions, severe pest pressure, resistance development, pesticide cancellations, etc.). Claims of severe pest or disease pressure must be documented with data or written testimony of qualified experts. If the request is being made prior to the existence of an emergency condition, a detailed explanation of why such emergency condition is expected must be submitted. In addition a "threshold level" should be specified, above which an emergency condition would be deemed to exist. Examples of threshold levels include a specified number of plant pests per plant, some level of rainfall occurring within a specific timeframe, the presence of weeds at a given crop stage, or some percentage of crop

defoliation due to a pest. Once a pest population or a situation progressed to this threshold level, use under the exemption would be allowed.

If resistance development, phytotoxicity, or similar claims are the basis for the emergency exemption, the applicant must include evidence (in the form of field or laboratory data) to support the claim. Written testimony from qualified experts may be considered when data are not available.

If yield loss is being claimed, studies comparing the proposed pesticide with existing registered alternatives should be provided.

3. **ADDITIONAL BENEFITS INFORMATION:** In those instances where the EPA determines that a significant risk exists from a proposed use, an in-depth benefit analysis will be conducted. Economic impacts of the following types will be considered whenever they are fully addressed in the application:

- a. Impacts at the pesticide user level.
- b. Measurable change in price and availability of the commodity to consumers.
- c. Measurable reduction in sales and/or employment of organizations supplying the affected producers.
- d. Measurable reduction in business volume and/or employment of organization marketing the output of the affected producers.
- e. Measurable reduction in the economic base, including employment of communities affected by the supplier and marketing organization.

Any of the above information or any non-economic or qualitative information which describes the benefits from using the pesticide will also be taken into consideration by EPA.

4. **DISCUSSION OF ECONOMIC LOSS:** Include a discussion of anticipated economic loss associated with the emergency condition.

The EPA requires five (5) years of yield and price data along with cost of production data (either five years of production cost data or a crop budget) to complete an economic analysis. This information should include the cost of pesticides or other pest control practices used over the last five years and the cost of the pesticide requested under the exemption. Whenever possible these costs should include both materials and application. The sample table attached at the end of this instruction packet should be used as a guide for providing suitable data for EPA's analysis.

If the five years of requested data includes data from abnormal years, either favorable (ideal growing conditions) or unfavorable (drought), this should be explained in the discussion and an alternative estimate of the normal range in profitability provided. The

request should fully explain how the alternative estimate of the normal range in profitability was derived.

If production cost data are not available, a best estimate of the cost of production should be provided. The data submitted should pertain to the area within the state impacted by the emergency. Be cautious about submitting statewide data. Statewide data are generally inadequate for demonstrating the nature and extent of a problem, unless the problem exists on the vast majority of the crop acreage within the State.

In addition to the above data, an estimate of the net and gross revenues with and without the proposed use must be submitted. The estimated revenues without the proposed use must be calculated based on the next best registered alternative pesticide or cultural practice being utilized. The revenue estimates should also be based on average expected yield reductions, not the maximum potential yield loss. If a reduction in quality is the nature of the emergency, provide information on the proportion of yield falling into each grade over the past five years and the effect of the emergency on quality of production (provide prices for each grade over the last five years).

In evaluating the significance of an economic loss for productive activities, EPA will also consider whether the loss would affect the long-term financial viability expected for the activity. For example, an enterprise may face a situation where, due to circumstances beyond its control (e.g., bad weather), it must have a remarkably good upcoming crop year to remain financially viable. Even though profits, without an exemption, are expected to be within the historical range, this will not be sufficient to make up for the previous crop failures. The enterprise will only realize the above-average profits needed to assure its long-term financial viability if an emergency exemption is granted to control an emergency pest problem. In such a situation, an emergency exemption could be granted even though profits without the exemption are expected to be within the historical range.

When the above information is not applicable because the exemption is requested for purposes unrelated to agricultural production, such as for protection of structures, museum pieces, or park land, an applicant should explain the inapplicability, discuss the expected economic losses in other reasonable terms, and provide the best available supporting data.

Five Year History

<i>Year</i>	<i>Yield/Acre</i>	<i>Price Per</i>	<i>Gross</i>	<i>Cost/Acre</i>	<i>Net</i>
-------------	-------------------	------------------	--------------	------------------	------------

<i>(Previous 5 Years)</i>	<i>(tons, lbs., etc)</i>	<i>Unit (\$)</i>	<i>Revenue/Acre (\$)</i>	<i>(\$)</i>	<i>Revenue/Acre (\$)</i>
1995					
1996					
1997					
1998					
1999					
Average					

Current Year

2000 Estimates

<i>With Product X</i>					
<i>Without Product X</i>					

C. SECTION 18 LABELS

In December 2000 the following state rules (WAC 16-228-1400[2]) were adopted which require Section 18 labels for pesticides distributed under an emergency exemption:

Any pesticide exempted from registration under the provisions of section 18 of FIFRA must be labeled as follows:

(a) Pesticides distributed under section 18 of FIFRA must be accompanied by a label approved by the department prior to distribution. All conditions set forth in the document granting the emergency exemption and all other requirements determined to be necessary by the department must be included on the label.

(b) In situations where a label cannot be developed and approved prior to the intended use period, the department may allow the use of the document granting the emergency exemption in lieu of labeling. Conditions set forth as part of the granting

document, and any attached or associated documentation from the department shall be considered labeling for purposes of enforcement.

The Registration Specialist assigned to your request can give you specific guidance on what WSDA will require on the Section 18 label. In general, you will need to include the directions for use and all other restrictions and conditions specified under Section 4 of the request that WSDA submits to EPA. In addition, other conditions and restrictions may be required by either WSDA or EPA. Please be aware that the granting document issued by the EPA may not include all necessary label requirements.

WAIVER OF LIABILITY STATEMENTS

Waiver of liability statements are used to limit product liability and are only applicable for crops grown on very limited acreage (e.g. some seed crops). EPA is opposed to enforcing limitations of user's rights, and will only allow certain waiver language. The following language is currently acceptable to EPA:

“(Registrant’s) Special Conditions and Disclaimer for use of (Product) on (Crop)”

“(Registrant) intends that this Section 18 label be distributed only by the (Grower Association) only to end users and/or growers who agree in writing to the terms and conditions required by the (Grower Association) including a waiver and release from all liability and indemnification by the user and/or grower of (Registrant), (Grower Association), and others for failure to perform and crop damage from the use of (Product) on (Crop). If such terms and conditions are unacceptable, return (Product) at once unopened.”

“This product when used on (Crop) may lead to crop injury, loss, or damage. (Registrant) recommends that the user and/or grower test this product in order to determine its suitability for such intended use. The (Grower Association) and (Registrant) make this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh the extent of potential injury associated with the use of this product. The decision to use or not to use this (Pesticide) must be made by each individual (Product) user and/or grower on the basis of possible crop injury from (Product), the severity of (Pest) infestation, the cost of alternative (Pest) controls, and other factors. (Registrant) intends that because of the risk of failure to perform or crop damage that all such use is at the user’s and/or grower’s risk.”